PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61F 2/01 — A1

(11) International Publication Number: WO 00/67665

(43) International Publication Date: 16 November 2000 (16.11.00)

(21) International Application Number: PCT/IE99/00035

(22) International Filing Date: 7 May 1999 (07.05.99)

(71) Applicant *(for all designated States except US)*: SALVIAC LIMITED [IE/IE]; 39–40 Upper Mount Street, Dublin 2 (IE).

(72) Inventors; and

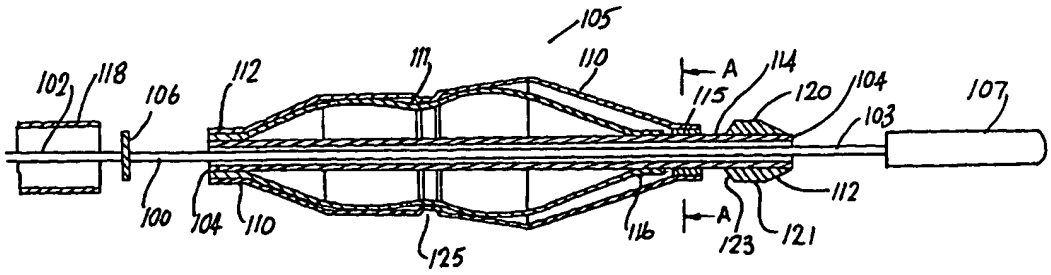
(75) Inventors/Applicants *(for US only)*: GILSON, Paul [IE/IE]; Uggool, Moycullen, County Galway (IE). GILVARRY, Michael [IE/IE]; Rathroe, Kilcon, Ballina, County Mayo (IE).

(74) Agents: O'BRIEN, John, A. et al.; John A O'Brien & Associates, Duncairn House, 3rd floor, 14 Carysfort Avenue, Blackrock, County Dublin (IE).

(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DE (Utility model), DK, DK (Utility model), EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: SUPPORT FRAME FOR EMBOLIC PROTECTION DEVICE



(57) Abstract

A support frame (30) for an embolic protection filter (31). Three arms (20, 21, 22) provide support for a proximal end of the filter body (31) and three arms (23, 24, 25) provide support for a distal end of the filter body (31). In this many loading and deployment forces are reduced.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

"SUPPORT FRAME FOR EMBOLIC PROTECTION DEVICE"

This invention relates to a filter element for a transcatheter embolic protection device.

Introduction

The invention is particularly concerned with filter elements for transcatheter embolic protection devices of the type described in our previously filed PCT Patent Application No. PCT/IE98/00093 the contents of which are incorporated herein by reference. One type of such embolic filter essentially comprises a filter body mounted on an associated collapsible support frame which can be collapsed against the guide wire by means of a catheter for deployment of the filter through a patient's vascular system. Upon retraction of the catheter the support frame and filter body expand outwardly from the guidewire across a blood vessel within which the filter is positioned to filter blood flowing through the blood vessel.

The support structure is generally of shaped memory material such as nitinol which provides the circumferential pressure on expansion to secure the filter bodies in a close fit within the vessel. When the filter element is being pulled through a small diameter conduit or opening, there are certain forces exerted on the support frame. The first is on entry of the proximal end into the tube and when the whole of the proximal end has been inserted into the tube and the distal end is about to be inserted into the catheter tube. Considerable loading forces are generated which in some cases require considerable retraction forces to overcome.

The present invention is directed towards overcoming this problem.

Statements of Invention

According to the invention there is provided an embolic protection device comprising:

a collapsible filter element for delivery through a vascular system of a patient;

the filter being movable between a collapsed stored position for movement through the vascular system, and an expanded position for occluding a blood vessel such that blood passing through the blood vessel is delivered through the filter element;

the filter element comprising a collapsible filter body and a filter support frame;

the collapsible filter body having an inlet end and an outlet end, the inlet end of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body, the outlet end of the filter body having a plurality of outlet openings sized to allow through passage of blood but to retain undesired embolic material within the filter body;

the filter support frame being movable between a collapsed position for movement through the vascular system and an extended outwardly projecting position to support the filter body in the expanded position;

characterised in that

the filter support frame comprises a plurality of support elements, some of the support elements providing support for a first portion of the filter body

and others of the support elements providing support for a second portion of the filter body.

In a preferred embodiment of the invention the first portion is a proximal portion of the filter body which is supported by proximal support elements.

In one embodiment of the invention the second portion is a distal portion of the filter body which is supported by distal support elements.

The proximal support elements preferably comprise a plurality of proximal support arms. Preferably there are three substantially equi-spaced proximal support arms.

Preferably the distal support elements comprise a plurality of distal support arms. Preferably there are three substantially equi-spaced distal support arms.

Brief Description of the Drawings

The invention will be more clearly understood by the following description of some of the embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which: -

Fig. 1 is partially sectioned elevational view an embolic protection device;

Fig. 2 is a schematic sectional elevational view of the embolic protection device of Fig. 1;

Fig. 3 is a detail sectional view of portion of the device of Fig. 1;

Fig. 4 is a longitudinal cross sectional view of the device of Fig. 1;

Fig. 5 is a cross sectional view of a distal end of the device of Fig. 1;

Fig. 6 is a view on the line A-A in Fig. 5;

Fig. 7 is a perspective view of a filter body of the device of Figs. 1 to 6;

Fig. 8 is a side elevational view of the filter body of Fig. 7;

Fig. 9 is a view on a proximal end of the filter body;

Fig. 10 is a perspective view of a support frame of the device of Figs. 1 to 6;

Fig. 11 is a side elevational view of the support frame;

Fig. 12 is a perspective view illustrating the manufacture of the support frame;

Fig. 13 is a view of the support frame and filter element assembly;

Fig. 14 is a longitudinal cross sectional view of a filter element according to the invention;

Fig. 15 is a longitudinal cross sectional view a support frame of the filter element of Fig. 14;

Fig. 16 is a cross sectional on the line III-III of Fig. 15;

Fig. 17 is a cross sectional view on the line IV-IV of Fig. 15;

Fig. 18 is a cross sectional view on the line V-V of Fig. 15; and

Fig. 19 is a longitudinal cross section view of another support frame.

Detailed Description

Referring to Figs. 1 to 13 there is illustrated an embolic protection device as described in our co-pending Application PCT/IE98/00093 indicated generally by the reference number 100. The device 100 has a guidewire 101 with a proximal end 102 and a distal end 103. A tubular sleeve 104 is slidably mounted on the guidewire 101. A collapsible filter 105 is mounted on the sleeve 104, the filter 105 being movable between a collapsed stored position against the sleeve 104 and an expanded position as shown in the drawings extended outwardly of the sleeve 104 for deployment in a blood vessel.

The sleeve 104 is slidable on the guidewire 101 between a pair of spaced-apart end stops, namely an inner stop 106 and an outer stop which in this case is formed by a spring tip 107 at the distal end 103 of the guidewire 101.

The filter 105 comprises a filter body 110 mounted over a collapsible support frame 111. The filter body 110 is mounted to the sleeve 104 at each end, the body 110 being rigidly attached to a proximal end 112 of the sleeve 104 and the body 110 being attached to a collar 115 which is slidable along a distal end 114 of the sleeve 104. Thus the distal end of the body 110 is longitudinally slidable along the sleeve 104. The support frame 111 is also fixed at the proximal end 112 of the sleeve 104. A distal end 116 of the support frame 111 is not attached to the sleeve 104 and is thus also free to move longitudinally along the sleeve 104 to facilitate collapsing the support frame 111 against the sleeve 104. The support frame 111 is such that it is naturally expanded as shown in the drawings and can be collapsed inwardly against the sleeve 104 for loading in a catheter 118 or the like.

The filter body 105 has large proximal inlet openings 117 and small distal outlet openings 119. The proximal inlet openings 117 allow blood and embolic material

to enter the filter body, however, the distal outlet openings 119 allow through passage of blood but retain undesired embolic material within the filter body.

An olive guide 120 is mounted at a distal end of the sleeve 104 and has a cylindrical central portion 121 with tapered ends 122, 123. The distal end 122 may be an arrowhead configuration for smooth transition between the catheter and olive surfaces. The support frame 111 is shaped to provide a circumferential groove 125 in the filter body 110. If the filter is too large for a vessel, the body may crease and this groove 125 ensures any crease does not propagate along the filter.

Enlarged openings are provided at a proximal end of the filter body 110 to allow ingress of blood and embolic material into an interior of the body 110.

In use, the filter 105 is mounted in a collapsed state within a distal end of the catheter 118 and delivered to a deployment site. When the filter is correctly positioned the catheter 118 is retracted allowing the support frame 111 to expand expanding the filter body 110 across the vessel in which the filter is mounted. Blood and emboli can enter the enlarged openings at a proximal end of the filter body 110. The blood will pass through the net wall, however, the openings or pores in the net are sized so as to retain the embolic material. After use the catheter is delivered along the guidewire 101 and slid over the filter 105 engaging the proximal inlet end 112 first to close the openings and then gradually collapsing the filter body against the sleeve 104 as the catheter 118 advances over the filter 105. Once the filter 105 is fully loaded in the catheter 118, it can then be withdrawn.

It will be noted that a proximal end of the filter is fixed and a distal end of the filter is longitudinally movable along the sleeve to facilitate collapsing of the filter body.

Further, the catheter engages the proximal end of the filter body first thus closing the filter body inlet and preventing escape of embolic material from the filter body as the filter body is being collapsed.

The outer filter body 110 is preferably of a resilient biocompatible elastomeric material. The material may be a polyurethane based material. There are a series of commercially available polyurethane materials that may be suitable. These are typically based on polyether or polycarbonate or silicone macroglycols together with diisocyanate and a diol or diamine or alkanolamine or water chain extender. Examples of these are described in EP-A-461,375 and US 5,621, 065. In addition, polyurethane elastomers manufactured from polycarbonate polyols as described in US 5,254,622 (Szycher) are also suitable.

The filter material may also be a biostable polycarbonate urethane article an example of which may be prepared by reaction of an isocyanate, a chain extender and a polycarbonate copolymer polyol of alkyl carbonates. This material is described in our co-pending PCT Application No. IE98/00091, filed November 9, 1998, the entire contents of which are incorporated herein by reference. The filter material may be manufactured from a block and cut into a desired shape. However the filter is preferably formed by dipping a rod of desired geometry into a solution of the material which coats the rod. The rod is then dissolved. The final geometry of the filter may be determined in the dipping step or the final geometry may be achieved in a finishing operation. Typically the finishing operations involve processes such as mechanical machining operations, laser machining or chemical machining.

The filter body is of hollow construction and is formed as described above by dipping a rod in a solution of polymeric material to coat the rod. The rod is then dissolved, leaving a hollow body polymeric material. The rod may be of an acrylic material which is dissolved by a suitable solvent such as acetone.

The polymeric body thus formed is machined to the shape illustrated in Figs. 1 to 13. The final machined filter body comprises an inlet or proximal portion 210 with a proximal neck 212, and outlet or distal portion 213 with a distal neck 214, and an intermediate portion 215 between the proximal and distal portions.

The inlet holes 117 are provided in the proximal portion 210 which allow the blood and embolic material to flow into the filter body. In this case the proximal portion 210 is of generally conical shape to maximise the hole size.

The intermediate portion 215 is also hollow and in this case is of generally cylindrical construction. This is important in ensuring more than simple point contact with the surrounding blood vessel. The cylindrical structure allows the filter body to come into soft contact with the blood vessel to avoid damaging the vessel wall.

The intermediate portion 215 is provided with a radial stiffening means, in this case in the form of a radial strengthening ring or rim 220. The ring 220 provides localised stiffening of the filter body without stiffening the material in contact with the vessel. Such an arrangement provides appropriate structural strength so that line apposition of the filter body to the vessel wall is achieved. It is expected that other geometrics of stiffening means will achieve a similar result.

The tubular intermediate portion 215 is also important in maintaining the stability of the filter body in situ to retain captured emboli and to ensure that flow around the filter is minimised. For optimum stability we have found that the ratio of the axial length of the intermediate portion 215 of the filter body to the diameter of the intermediate portion 215 is preferably at least 0.5 and ideally greater than 1.0.

The collapsible support frame 111 has four foldable arms 290 which are collapsed for deployment and upon release extend outwardly to expand the filter body 110.

The support frame 111 can be manufactured from a range of metallic or polymeric components such as a shape memory alloy like nitinol or a shape memory polymer or a shaped stainless steel or metal with similar properties that will recover from the deformation sufficiently to cause the filter body 110 to open.

The support frame may be formed as illustrated in Fig. 12 by machining slots in a tube 291 of shape memory alloy such as nitinol. On machining, the unslotted distal end of the tube forms a distal collar 293 and the unslotted proximal end of the tube forms a proximal collar 294. In use, the distal collar 293 is slidably moveable along the tubular sleeve 104 which in turn is slidably mounted on the guidewire 101 for deployment and retrieval. The proximal collar 294 is fixed relative to the tubular sleeve 104.

To load the filter the sub assembly of the support frame and filter body is pulled back into the catheter 118 to engage the distal stop 107. The support arms 290 are hinged inwardly and the distal collar 293 moves forward along the tubular sleeve 104. As the support arms 290 enter the catheter 118 the filter body 110 stretches as the filter body collar 115 slides along the tubular sleeve 104 proximal to the olive 120. On deployment, the catheter 118 is retracted proximally along the guidewire 101 initially bringing the collapsed filter assembly with it until it engages the proximal stop 106. The catheter sleeve then begins to pull off the filter freeing the support arms 290 to expand and the filter body apposes the vessel wall.

For retrieval, a retrieval catheter is introduced by sliding it over the guidewire 101 until it is positioned at the proximal end of the filter body and support frame. Pulling the guidewire 101 will initially engage the distal stop 107 with the filter element and begin to pull it into the retrieval catheter. The initial travel into the delivery catheter acts to close the proximal openings of the filter element, thus entrapping the embolic load. As the filter continues to be pulled back the filter

body and the support frame are enveloped in the retrieval catheter. The collapsed filter may then be removed from the patient.

Referring to Figs. 14 to 18 there is illustrated a support frame indicated generally by the reference numeral 30 for a filter 31.

The filter support frame comprises a plurality of support elements some of which provide support for one portion of the filter body 31 and some of which provide support for another portion of the filter body 31. In this case there are six support arms, three arms 20, 21, 22 providing support for a proximal end of the filter body 31 and three arms 23, 24, 25 providing support for a distal end of the filter body 31.

In this way the loading forces are greatly reduced, while at the same time the integrity of the filter is maintained. Thus, the filter can be more easily loaded and retrieved.

Referring to Fig. 19 there is illustrated another support frame 40 similar to that of Figs. 14 to 18. In this case adequate support is provided while omitting the distal collar 293. This frame 40 is more easily formed and the same principle may be applied to other frames as those described above.

The invention is not limited to the embodiments hereinbefore described which may be varied in both construction and detail.

Claims

1. An embolic protection device comprising:

a collapsible filter element for delivery through a vascular system of a patient;

the filter being movable between a collapsed stored position for movement through the vascular system, and an expanded position for occluding a blood vessel such that blood passing through the blood vessel is delivered through the filter element;

the filter element comprising a collapsible filter body and a filter support frame;

the collapsible filter body having an inlet end and an outlet end, the inlet end of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body, the outlet end of the filter body having a plurality of outlet openings sized to allow through passage of blood but to retain undesired embolic material within the filter body;

the filter support frame being movable between a collapsed position for movement through the vascular system and an extended outwardly projecting position to support the filter body in the expanded position;

characterised in that

the filter support frame comprises a plurality of support elements, some of the support elements providing support for a first portion of

the filter body and others of the support elements providing support for a second portion of the filter body.

2. An embolic protection device as claimed in claim 1 wherein the first portion is a proximal portion of the filter body which is supported by proximal support elements.

3. An embolic protection device as claimed in claim 1 or 2 wherein the second portion is a distal portion of the filter body which is supported by distal support elements.

4. An embolic protection device as claimed in claim 2 or 3 wherein the proximal support elements comprise a plurality of proximal support arms.

5. An embolic protection device as claimed in claim 4 wherein there are three substantially equi-spaced proximal support arms.

6. An embolic protection device as claimed in any of claims 3 to 5 wherein the distal support elements comprise a plurality of distal support arms.

7. An embolic protection device as claimed in claim 6 wherein there are three substantially equi-spaced distal support arms.

8. An embolic protection device substantially as hereinbefore described with reference to the accompanying drawings.

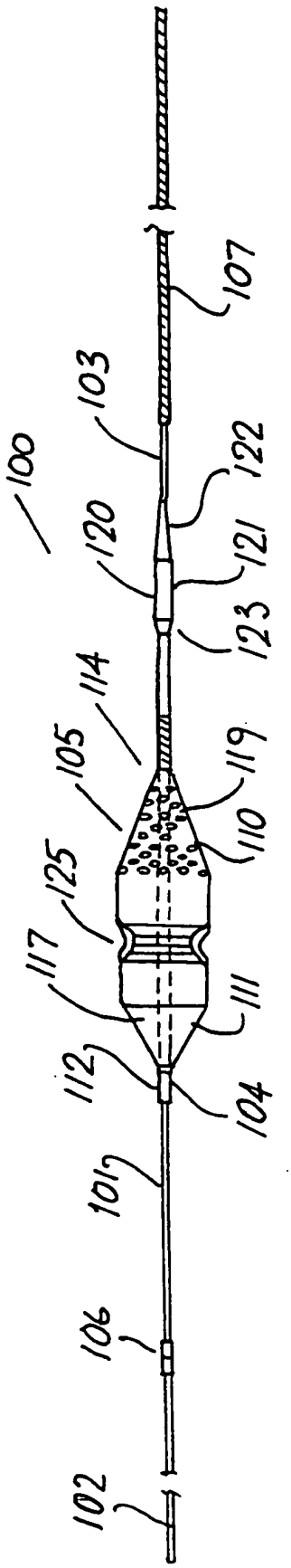

100
102
103
104
105
106
107
110
111
112
114
117
119
120
121
122
123
125
101

Fig.1

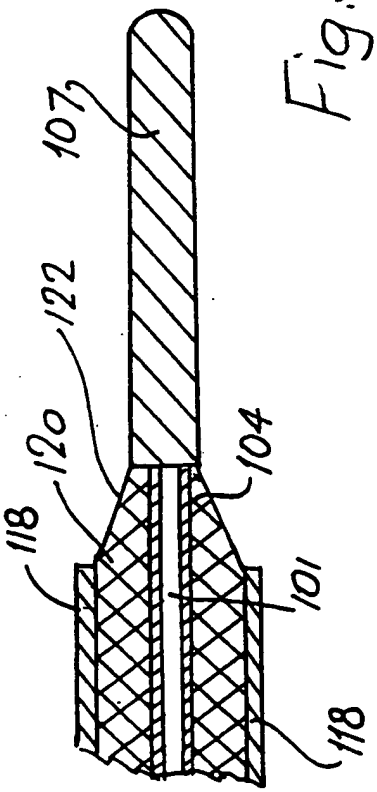

107
122
120
104
118
101
118

Fig.3

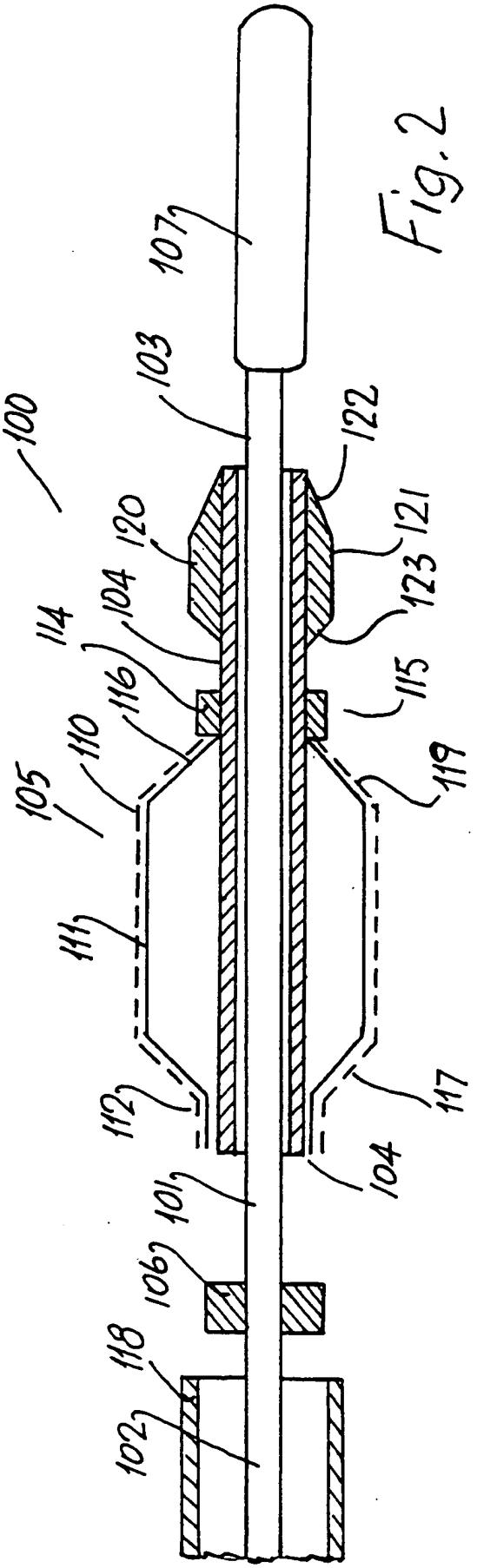

100
107
103
122
120
121
123
104
114
116
115
110
105
119
111
112
117
104
101
106
118
102

Fig.2

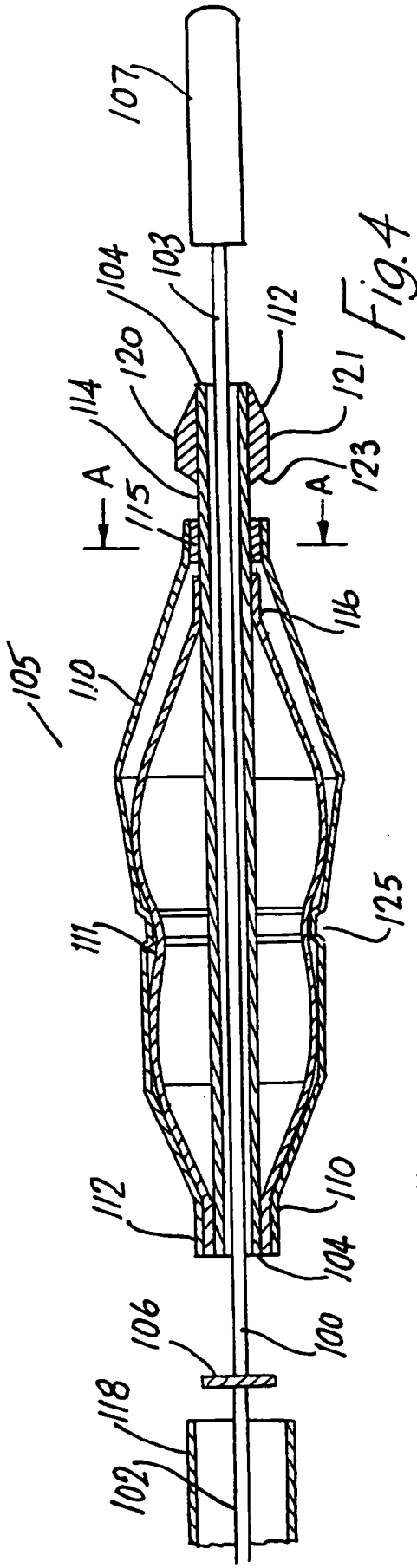


Fig. 4

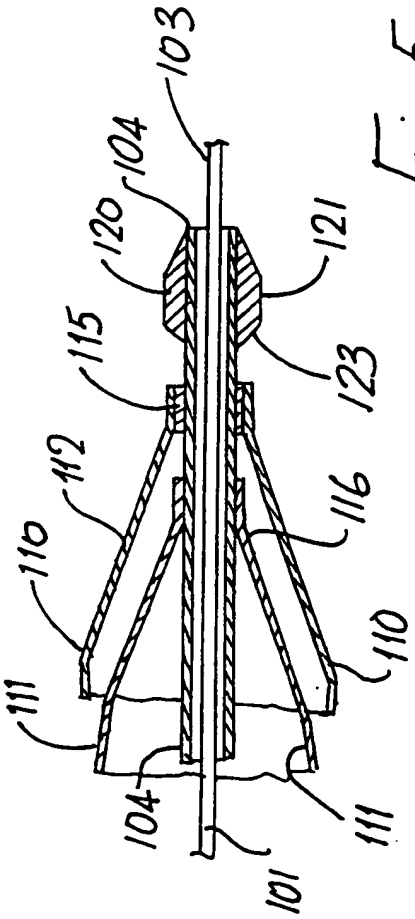


Fig. 5

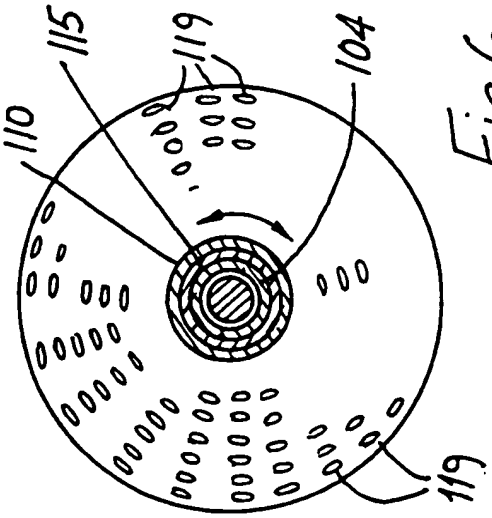


Fig. 6

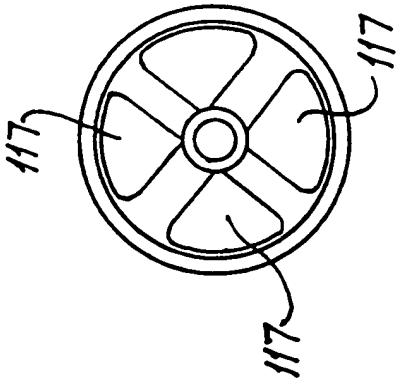


Fig. 9

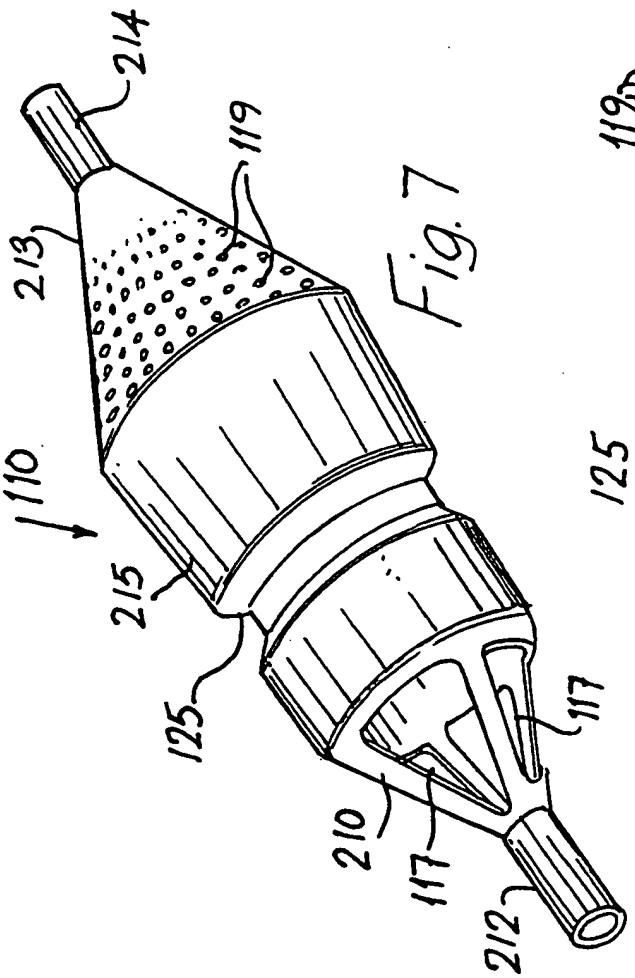


Fig. 7

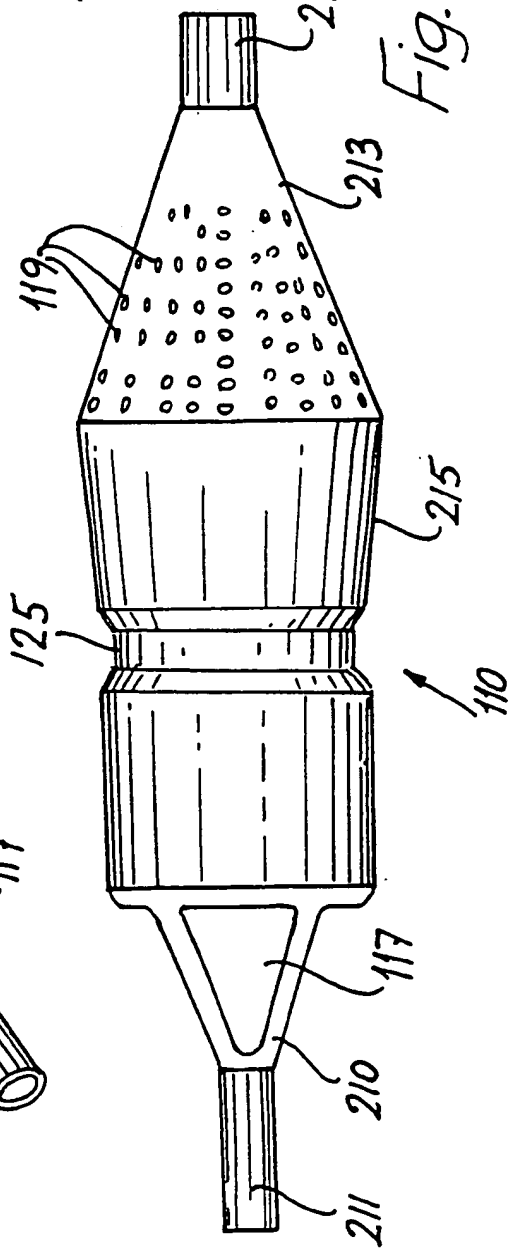


Fig. 8

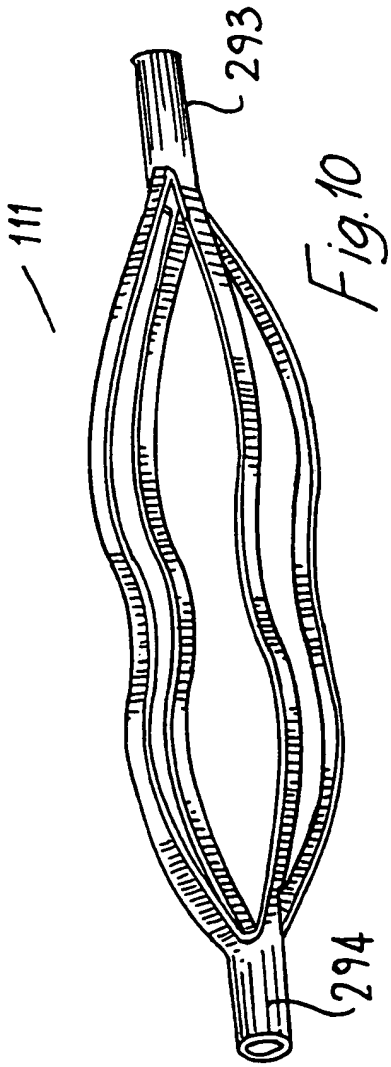


Fig. 10

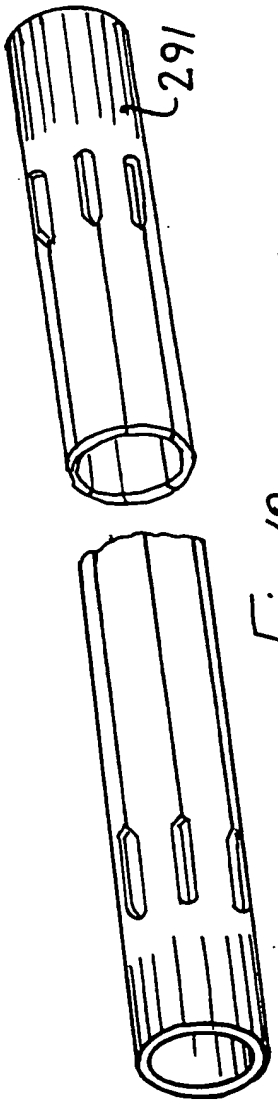


Fig. 12

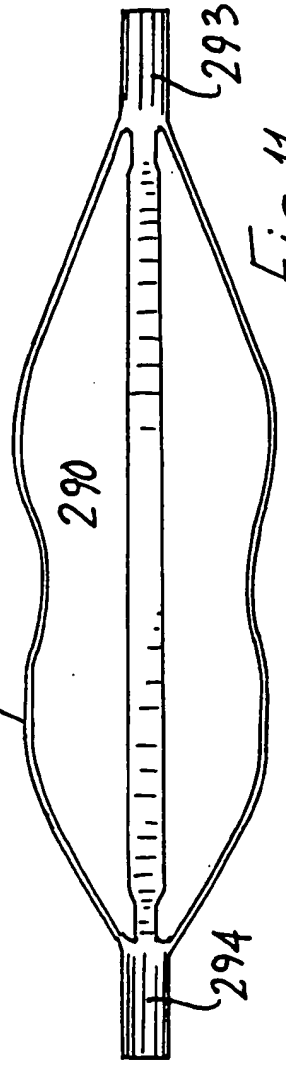


Fig. 11

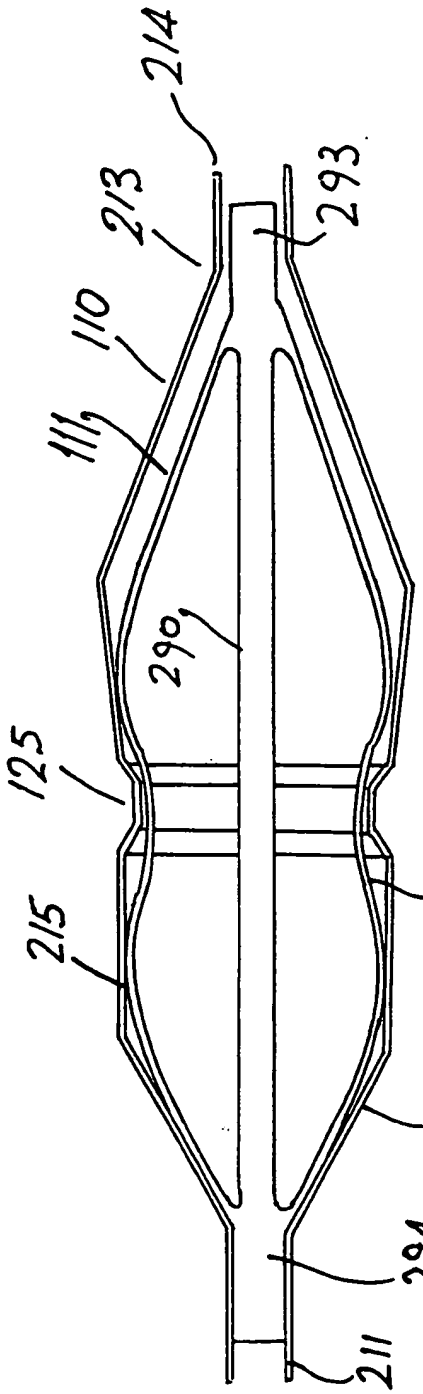


Fig. 13

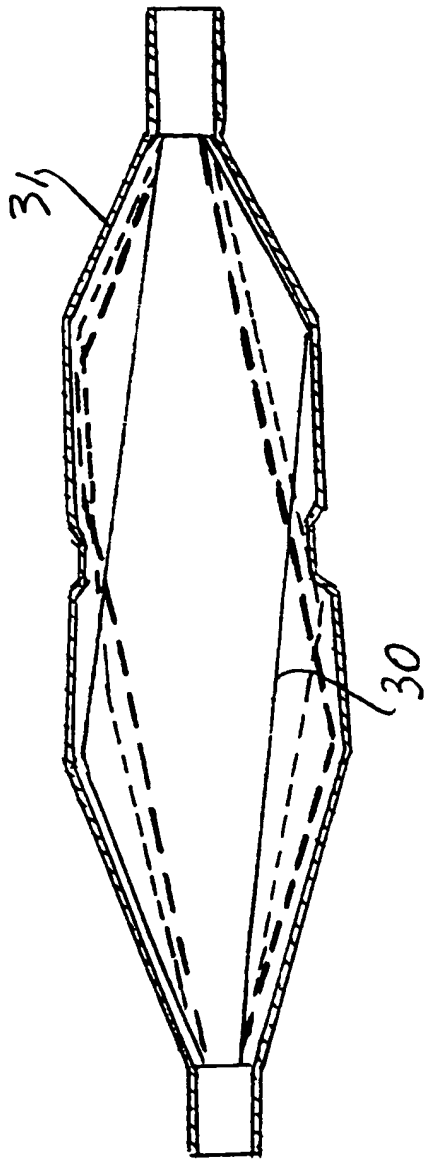


Fig. 14

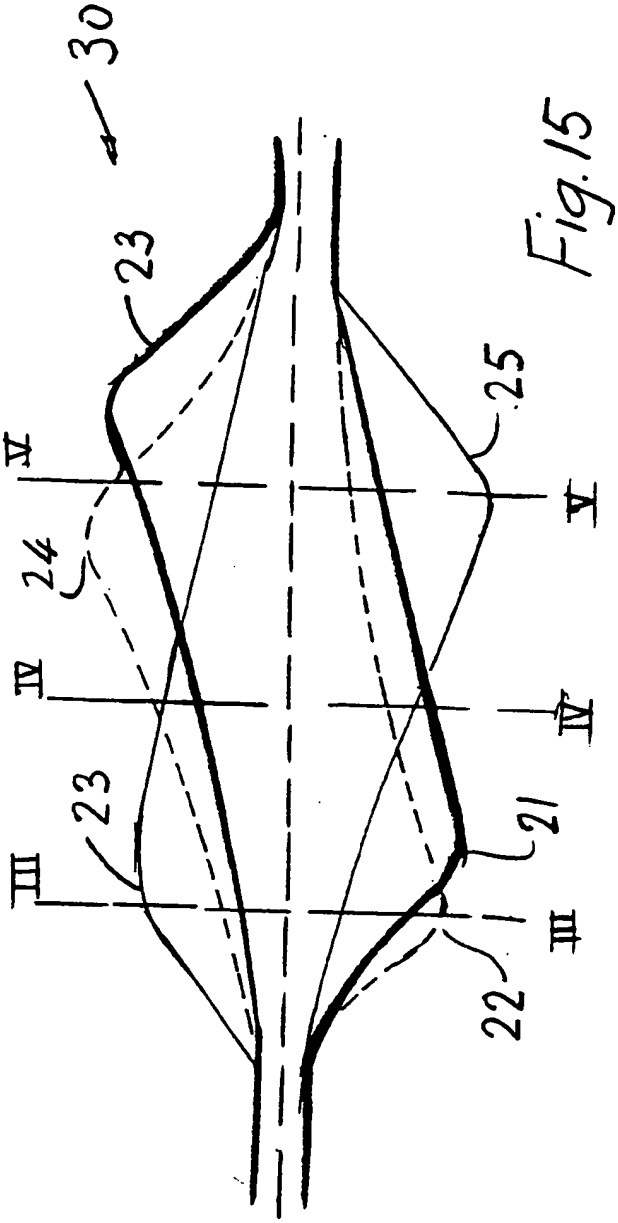


Fig. 15

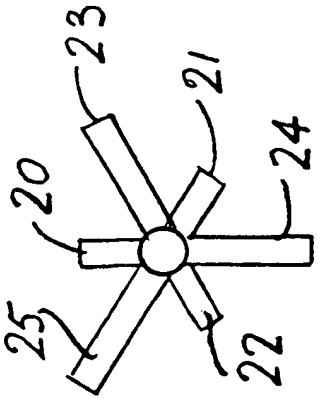


Fig. 18

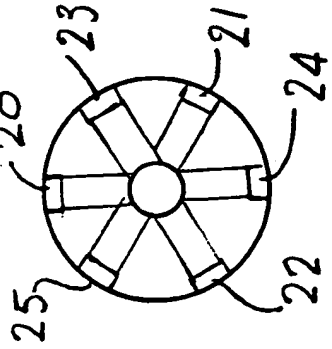


Fig. 17

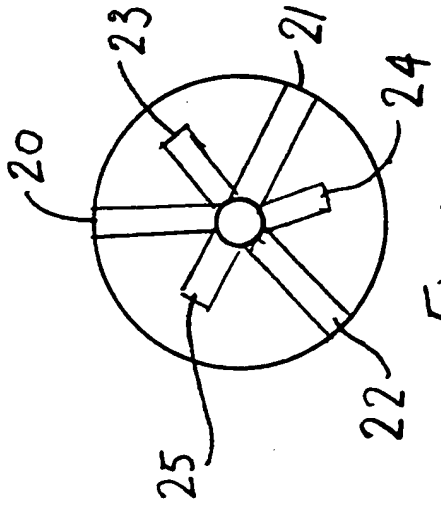


Fig. 16

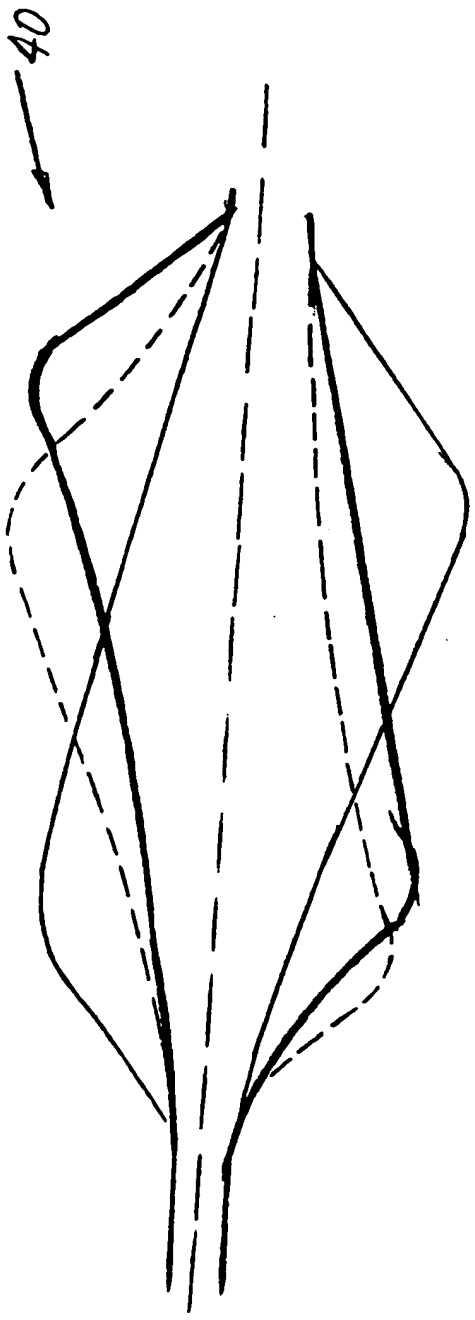


Fig. 19

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IE 99/00035

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category ³	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 16382 A (CARDEON CORPORATION) 8 April 1999 (1999-04-08) page 24, line 23 -page 25, line 4; figure 30	1
A	WO 98 39053 A (SCIMED LIFE SYSTEMS, INC.) 11 September 1998 (1998-09-11) abstract; figures	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

³ Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 December 1999	14/01/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Smith, C

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IE 99/00035

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 8
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
Rule 6.2(a) PCT

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IE 99/00035

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9916382 A	08-04-1999	AU 9321498 A	23-04-1999
WO 9839053 A	11-09-1998	US 5827324 A	27-10-1998
		EP 0934092 A	11-08-1999